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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | | | ATTORNEY DOCKET NO. |
|---|-------------|----------------------|---|--------------|---------------------|
| 08/477,983 | 06/07/95 | RUBIN | | J | 40399/321/NI |
| - HM12/1124 | | | ٦ | EXAMINER | |
| STEPHEN A BENT | | | | SAOUD, | С |
| FOLEY & LARDNER | | | | ART UNIT | PAPER NUMBER |
| SUITE 500 3000 K STREET NW WASHINGTON DC 20007-5109 | | | | 1646 | 26 |
| WHOTTINGTON | PC 20007-51 | 103 | | DATE MAILED: | 11/24/99 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



Office Action Summary

Application No. 08/477,983

Applicant(s)

Examiner

Christine Saoud

Group Art Unit 1646

RUBIN et al.



| X Responsive to communication(s) filed on Oct 6, 1999 | · |
|--|---|
| ★ This action is FINAL. | |
| ☐ Since this application is in condition for allowance except for for in accordance with the practice under Ex parte Quayle, 1935 (| |
| A shortened statutory period for response to this action is set to e is longer, from the mailing date of this communication. Failure to application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a). | respond within the period for response will cause the |
| Disposition of Claims | |
| | is/are pending in the application. |
| Of the above, claim(s) | is/are withdrawn from consideration. |
| Claim(s) | • |
| | |
| ☐ Claim(s) | |
| ☐ Claims | |
| Application Papers | |
| ☐ See the attached Notice of Draftsperson's Patent Drawing F | Review, PTO-948. |
| ☐ The drawing(s) filed on is/are objected | I to by the Examiner. |
| ☐ The proposed drawing correction, filed on | |
| ☐ The specification is objected to by the Examiner. | |
| \square The oath or declaration is objected to by the Examiner. | |
| Priority under 35 U.S.C. § 119 | |
| Acknowledgement is made of a claim for foreign priority un | der 35 U.S.C. § 119(a)-(d). |
| ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the | he priority documents have been |
| received. | |
| ☐ received in Application No. (Series Code/Serial Number | er) |
| \square received in this national stage application from the In | ternational Bureau (PCT Rule 17.2(a)). |
| *Certified copies not received: | |
| Acknowledgement is made of a claim for domestic priority in | under 35 U.S.C. § 119(e). |
| Attachment(s) | |
| ☐ Notice of References Cited, PTO-892 | |
| Information Disclosure Statement(s), PTO-1449, Paper No(s | 3) |
| ☐ Interview Summary, PTO-413 | |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 | |
| ☐ Notice of Informal Patent Application, PTO-152 | |
| | |
| SEE OFFICE ACTION ON THE | FOLLOWING PAGES |

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DETAILED ACTION

Response to Amendment

- 1. Claim 80 has been canceled, claims 45-46, 51, 53, 58, 63, 67, 71, 78-79, and 81-85 have been amended and claims 89-91 have been added as requested in the amendment of paper #25, filed 06 October 1999. Claims 44-79 and 81-91 are pending in the instant application.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4. Applicant's arguments filed 06 October 1999 have been fully considered but they are not deemed to be persuasive.

Specification

5. The substitute specification filed 06 October 1999 has been received and entered into the instant application.

Double Patenting

6. Claims 44-79 and 81-91 are provisionally rejected under the judicially created doctrine of double patenting over claims 63-76 of copending Application No. 08/455,620 for the reasons of

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record in paper #23. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicant indicates that they will attend to such issues upon indication of allowable subject matter. Applicant should note that the claims cannot be indicated to be allowable until all rejections are resolved in the application, including double patenting rejections.

Claim Rejections - 35 USC § 112

7. Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 is directed to a polypeptide which has a substitution "within residues 65-157 and 161-189", however, it is not possible to have a single substitution within two different regions at the same time (i.e. this would be two substitutions). This ground of rejection could be avoided by altering the claim language to something like: "which has a conservative amino acid substitution at a residue selected from the group consisting of residues 65-157 and 161-189 of the amino acid sequence of Figure 7".

8. Claims 45-46, 48-79 and 81-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention for the reasons of record in paper #23 as applied to claims 45-46, and 48-88.

Claims 45-46, 48-77, 81-82, 84-85 and 88 refer to polypeptides which stimulate BALB/MK cells to a greater degree compared to NIH/3T3 cells. However, the specification only provides for a polypeptide which stimulates BALB/MK cells 50 times greater than NIH/3T3 cells, rather than the varying degrees which are now recited in the claims (support is based on the previously filed claims). The instant specification does not provide for these new limitations of stimulation, nor does it provide for KGF polypeptides that differ in their ability to stimulate BALB/MK cells. A single KGF polypeptide is provided and it has the amino acid sequence as depicted in Figure 7, absent evidence to the contrary. Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, absent evidence to the contrary. Applicant did not address this ground of rejection in the response of paper #25, therefore it is being maintained.

Conclusion

- 9. No claim is allowed.
- 10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D. November 19, 1999

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SUPERVISORY PATENT EXAMINER